# National Institutes of Health

## *Summary of the FY 2004 President's Budget*


February 3, 2003

**NIH Budget at a Glance**

| | | % Change |
|---|---|---|
| FY 2002 Actual | $23,558.9 m | |
| FY 2003 Amended President's Budget | $27,343.4 m | 16.1% |
| FY 2004 President's Budget | $27,892.8 m | 1.8% |
| Number of Competing RPGs | 10,509 | |
| Total Number of RPGs w/o SBIR/STTR | 37,467 | |

The mission of the National Institutes of Health (NIH) is to expand fundamental knowledge about the nature and behavior of living systems and to improve and develop new strategies for the diagnosis, treatment, and prevention of disease and communicate the results of research with the goal of improving health. The 27 Institutes and Centers, which comprise the NIH, support research and researchers working in universities, medical centers, hospitals, and research institutions in every State and territory in the Nation and in many countries around the world. The NIH also conducts research in its own laboratories. In order to help ensure that there is a continuing cadre of outstanding scientists for the future and that there are facilities in which to conduct this research, the Agency supports research training, career development, and some buildings and facilities programs.

In fulfilling its mission, the NIH leadership manages a diverse portfolio of research founded on both public health need and scientific opportunity. It does so with the advice of, and in collaboration with, our partners: scientists, patients, physicians, health care payers and providers, the public, the Congress, and the Administration. The two-tiered NIH peer review system is critical to ensuring that only the best proposals are funded from approximately 44,000 research and training applications received each year.

After five years of outstanding growth that effectively doubled the NIH budget, the FY 2004 Budget provides a significant investment to ensure that the momentum gained over the last five years is sustained.

The FY 2004 program level for the NIH, based on current law, is $27,893 million, an increase of $549 million or 2 percent over the FY 2003 Amended President's Budget. Included in this request is $79 million to be requested from the Veteran's Administration/Housing and Urban Development Appropriations Subcommittee for the Superfund research program and $150 million for the Type I Diabetes Initiative appropriated through P.L. 107-360. When adjusted for one-time facilities costs in FY 2003, the total available for NIH non-biodefense research programs increases by 4.3 percent. The NIH President's Budget request to the Labor/Health and Human Services/Education Appropriations Subcommittee is $27,664 million.

Support for AIDS research will increase by $110 million, or percent over the FY 2003 Amended President's Budget, for a total of $2,870 million.

The budget request for NIH also includes $100 million in NIAID to continue HHS contributions initiated in FY 2002 to the Global Fund to Fight HIV/AIDS, Malaria, and Tuberculosis.

The FY 2003 Amended President's Budget provided $361.3 million to accelerate the completion of the John Edward Porter Neuroscience Research Center and construct additional BioSafety Labs. This will allow NIH to more quickly establish the homeland security research infrastructure.

The FY 2004 Budget supports NIH's request of $1,625 million for biodefense research. The budget for Biodefense research more than doubles (+117%) from the FY 2003 Amended President's Budget. Research in this case excludes facilities (intramural and extramural) and, in making the comparison, excludes from the calculation the one-time anthrax vaccine costs in FY 2003. NIH will coordinate its homeland security research with the Department of Homeland Security and the Office of Science Technology Policy to ensure adequate balance in coverage across the spectrum of terrorist threats to human health.

## Research Initiatives

Given its extensive and complex program portfolio and the need to invest funds productively for the health and defense of the American people, NIH launched an Agency-wide effort to identify the critical roadblocks and knowledge gaps that constrain rapid advances in biomedical research progress.

The NIH Roadmap is the result of an ongoing series of consultations with scientists charged with thinking broadly about the future. It is comprised of three broad initiatives which will exploit and extend past discoveries to meet tomorrow's challenges:

- New Pathways to Discovery
- Multidisciplinary Research Teams of the Future
- Re-engineering the Clinical Research Enterprise

### New Pathways to Discovery: New Approaches and Technologies

To understand the role of genetics in disease, we must comprehend how genes manage the production of proteins, the building blocks of the body's cells and tissues. That means identifying all of the components of the human cell – all of the genes and their common variants, all of the regulatory signals that control gene expression, and all of the proteins those genes encode. Even more importantly, we must understand how those components go awry in disease.

Biological processes are not simple or static. Integrative research is focused on understanding how complex biological systems operate, with the goal of being able to predict the behavior of the system in response to disturbances such as disease or experimental medications. By understanding how the components of a network interact, investigators can identify the many and varied parts of the system that play a role in the disease process. And because most diseases involve multiple points of failure in several key biological pathways, this research is becoming ever more critical.

Regenerative medicine seeks to revolutionize the ways we improve the length and quality of life by restoring, maintaining, or enhancing tissue and organ function. It involves the merging of several fields, including tissue engineering, biomaterials development, and stem cell biology. Tissue engineering includes research on the growth of regenerating cells in two and three-dimensional matrices for use in transplantation therapies to replace a damaged or diseased organ. Novel biomaterials are being designed to provide both physical and chemical cues, which direct the organization, growth, and differentiation of cells in the process of forming functional tissue.

Structural biology, the study of protein structures, yields penetrating insights into both biological function and disease and the design and development of new drugs. Large and complex protein assemblies (a group of proteins that interact together) perform many of the numerous tasks in the cell. To date, NIH-funded researchers resolved over 18,000 protein structures. This work has led to the design of countless new drugs. The resolution of more large protein assemblies is a formidable challenge that must be met if we are to ensure the most efficient and effective drug development.

In recent years, two fields have stood out for their rapid progress and societal impact: biomedicine and computer science. The marriage of those two disciplines allows even more dramatic progress. Without major improvements in computational capability, the first draft sequence of the human genome could not have been obtained and distributed freely to all in 2001, ahead of schedule. Today, advances in biomedicine will depend significantly on computation and bioinformatics or data mining. One example of this dependence is seen in the clinical research enterprise, where, in the future, it will be possible to mine data from many patients to discover how to better treat each individual and to ask and answer questions that are currently not answerable.

Despite the recent and rapid discovery of biological targets with research and therapeutic potential, the identification of small molecules that selectively interact with and alter these targets is still a tedious and unpredictable process. Creating molecular libraries (comprehensive databases and repositories of chemical compounds, drugs, reagents, and molecular research tools) and enhancing access to screening services would facilitate the development and use of small molecules as novel research tools and potentially for new therapeutics.

Nanotechnology, the science of building materials from single atoms and molecules, could significantly improve, if not radically change, the prevention, detection, diagnosis, and treatment of diseases and disorders. Operating at the same small scale as biological processes, nanotechnology offers a unique vantage point from which to view and interact with basic life processes.

NIH plans to continue its investment in molecular imaging, a critical component of diagnostic tool development. Improved imaging technologies allow researchers to view complex structures such as protein assemblies, which carry out most cellular functions. Live and real time 3-D information not only provides researchers a key to understanding cell organization, but also crucial clinical data for understanding molecular processes which underlie complex disease. This, in turn, leads to better opportunities for disease intervention or prevention. This understanding will provide novel approaches to non-invasive diagnostics and monitoring, and minimally invasive therapy, for a wider range of organ systems and diseases.

**Multidisciplinary Research Teams of the Future**

There has been a fundamental shift in the way that science is being done in this country. While advances in genomics, proteomics, structural biology, systems biology, and bioinformatics have created unique opportunities for researchers to tackle complex biological and biomedical problems, a look inside the laboratories across the country reveals tremendous changes – changes in the workforce, the administration, the means and modes of collaboration, and in the training of investigators. The culture of individual investigators working in isolation – stoked by competition and fueled by ingenuity – is now being redirected to large teams that span university departments, disciplines, and geographical barriers. As we look to the future, the NIH will need to address the role of government in facilitating culture change and work with the private sector, universities, professional societies, and researchers to implement such change.

**Re-engineering the Clinical Research Enterprise**

A major NIH priority for the upcoming years is to rethink the technical and human infrastructure requirements for a more effective clinical research enterprise. A planning effort is underway to identify the major roadblocks and potential solutions. We will focus on a broad-based re-engineering effort with partnerships involving our sister Agencies, academic centers, community based professionals, industry, and patient groups. The ultimate goal of this effort will be to develop a more systematic and standardized national clinical research infrastructure with interoperable information systems to maximize the effectiveness of our investments in clinical investigations.

**Biodefense**

The FY 2004 NIH Request continues our efforts to expand our nation's biodefense capacity. The FY 04 level would provide $1,625 million. The apparent decrease from the FY 2003 Amended President's Budget is the result of completing the funding of new biodefense facilities in FY 2003. Excluding facilities funded in FY 2003 and the one-time anthrax vaccine procurement, support for biodefense research increases by 117 percent.

Under the leadership of the National Institute of Allergy and Infectious Diseases, NIH has developed a strategic plan to effectively target this proposed increase in several critical areas such as:

- Expanding basic research, including the addition of four Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases to provide and maintain the research and development capacity necessary for identifying and responding to emerging diseases and bioterrorism events;

- Expanding the number of candidate drugs and vaccines under research using the FDA's "animal model rule"; this rule is the principal approach to showing scientific "proof of concept" for a candidate drug or vaccine that is under development as a countermeasure to a potential agent of bioterrorism. NIH will also increase its interactions with collaborative partners in industry to foster translational research; and

- Expanding clinical research projects to support Phase I and II clinical trials of candidate vaccines/drugs, including a next generation smallpox vaccine, a plague vaccine and an ebola vaccine.

**Mechanism Discussion**

- Research Project Grants. The FY 2004 Budget allows NIH to award 10,509 competing research project grants, an increase of 344 competing RPGs over FY 2003.

- Full Funding. The FY 2004 Budget will fully fund 322 competing grants. NIH will undertake a study over the course of the year to determine the types of grants that can reasonably be fully funded from both the point of financial stewardship and scientific accountability. Following the study, other categories of grants may also be considered for multi-year funding.

- Grant cost management policy. NIH will manage its competing and non-competing grants in a responsible and prudent manner, holding average cost increase in the aggregate to 2.7 percent.

- NRSA awards. Promises for advancement in medical research are dependent on maintaining the supply of new investigators with new ideas. Stipend levels for the Ruth

L. Kirschstein National Research Service Award trainees will increase by 4 percent over Fiscal Year 2003 levels for predoctoral fellows, and from 4-1 percent, based on years of experience, for postdoctoral fellows.

- Diabetes and Obesity. The epidemic of obesity threatens the Nation's health by sharply increasing the incidence of type 2 diabetes, fatty liver disease, kidney failure, cardiovascular and other diseases. However, dramatic advances in our understanding of regulation of appetite and weight offer new opportunities to develop methods to treat obesity and to prevent type 2 diabetes and other obesity-related diseases. The FY 2004 President's budget request includes an increase of $14 million for expanded trans-NIH research programs in obesity and diabetes.

- IdeA Program. Also included in this budget request is an increase of $25 million, for a total of $210 million in support for the Institutional Development Award (IDeA) program. This increase supports NIH's continuing efforts to develop a critical mass of competitive biomedical researchers in states that have not fully participated in NIH research funding in the past.

- Children's Pharmaceuticals. An increase of $25 million is provided in R&D contracts to fund studies arising from the Best Pharmaceuticals for Children Act.

- Other New Investments. As an additional effort to accelerate fundamental discovery and translation of new knowledge into preventive and therapeutic strategies, the FY 2004 budget request for the Office of the Director includes an increase of $35 million for strategic "roadmap" initiatives. These funds will be allocated by the NIH Director to the Institutes and Centers to address critical roadblocks and knowledge gaps that currently constrain rapid progress in biomedical research. Three broad initiatives will be stimulated with these funds: 1) new pathways to discovery, which includes both new approaches and enabling technologies, such as a comprehensive parts list for biology, pathways and networks in health and disease, regenerative medicine, structural biology, molecular libraries, nanotechnology, computational biology and bioinformatics and molecular imaging; 2) multidisciplinary research teams of the future; and 3) re-engineering the clinical research enterprise. These efforts will allow the NIH to rethink the technical and human infrastructure required to translate findings from genetics and proteomics into front-line treatments used by health professionals on patients.

The FY 2004 President's Budget request reflects a $109 million reduction in the Information Technology (IT) Budget, which incorporates savings from ongoing IT consolidation efforts, including the streamlining or elimination of IT projects. NIH will fully implement Information Technology (IT) infrastructure consolidation by October 2003, therefore reducing infrastructure expenditure in FY 2004.

In FY 2004, NIH is requesting an additional 125 FTEs to support biodefense research activities and provide for management and oversight of the biodefense research program. NIH's FY 2004 budget supports the President's Management Agenda and includes $41 million in cost savings from consolidating administrative functions, organizational delayering to speed decision making processes, competitive sourcing, implementation of effective workforce planning and human capital management strategies, and adoption of other economies and efficiencies in administrative operations.

**NATIONAL INSTITUTES OF HEALTH**

Summary of Appropriations

(Dollars in thousands)

| Appropriation | FY 2002 Bud. Authority 1/2/3/4/8/ Includes AIDS | FY 2003 Amended Pres. Bud. 2/4/ Includes AIDS | FY 2004 Estimate Includes AIDS |
|---|---|---|---|
| NCI | $4,113,673 | $4,608,985 | $4,770,519 |
| NHLBI | 2,553,663 | 2,762,401 | 2,867,995 |
| NIDCR | 341,839 | 369,304 | 382,396 |
| NIDDK | 1,559,583 | 1,703,161 | 1,820,007 |
| NINDS | 1,309,418 | 1,416,421 | 1,468,926 |
| NIAID | 2,525,843 | 3,981,100 | 4,335,255 |
| NIGMS | 1,697,756 | 1,849,048 | 1,923,133 |
| NICHD | 1,109,368 | 1,194,891 | 1,245,371 |
| NEI | 579,540 | 625,076 | 648,299 |
| NIEHS | 563,329 | 608,882 | 630,774 |
| NIA | 890,816 | 957,626 | 994,411 |
| NIAMS | 447,423 | 485,481 | 502,778 |
| NIDCD | 341,126 | 365,734 | 380,377 |
| NIMH | 1,234,158 | 1,332,500 | 1,382,114 |
| NIDA | 892,082 | 959,979 | 995,614 |
| NIAAA | 382,839 | 414,919 | 430,121 |
| NINR | 120,175 | 129,703 | 134,579 |
| NHGRI | 427,935 | 457,792 | 478,072 |
| NIBIB | 261,733 | 270,494 | 282,109 |
| NCRR | 985,024 | 1,065,060 | 1,053,926 |
| NCCAM | 104,241 | 112,442 | 116,202 |
| NCMHD | 157,359 | 185,849 | 192,724 |
| FIC | 55,534 | 61,816 | 64,266 |
| NLM | 274,284 | 305,927 | 316,040 |
| OD 9/ | 253,463 | 273,952 | 317,983 |
| B&F | 295,879 | 769,100 | 80,000 |
| Subtotal | 23,478,083 | 27,267,643 | 27,813,991 |
| VA/HUD Approp. 6/ | 80,725 | 75,774 | 78,774 |
| Total, Prog. Level | 23,558,808 | 27,343,417 | 27,892,765 |
| Type 1 Diabetes 7/ | -97,000 | -100,000 | -150,000 |
| Total, B. A. | 23,461,808 | 27,243,417 | 27,742,765 |

1/ Reflects DHHS reduction of $9,273,000; Labor/Ed/DHHS rescission of $22,946,000; Gov't-wide rescission of $34,243,000; Global AIDS transfer of -$100,000,000; DHHS transfer of -$25,000,000.

2/ Comparable for transfers to NIBIB, and $583,000 transfer to the Department of Homeland Security.

3/ FY 2002 reflects real transfers and appropriations in all Institutes(+$97,000 to NIDDK for Diabetes; +$6,880 to NIDA from ONDCP)

4/ Comparable for OD program and FIC program transfers.

5/ FY 2002 amounts include $180 million appropriated to the PHS Emergency Fund Supplemental through the FY 2002 Department of Defense and Emergency Supplemental Appropriations for Recovery from the Response to Terrorist Attacks on the United States Act (P.L. 107-117).

6/ Includes supplemental from the Emergency Relief Fund of + $10.5 million in FY 2002.

7/ Funds available for diabetes research in accordance with the Balanced Budget Act of 1997 (FY 1998 through FY 2002) and P.L. 106-554 and P.L. 107-360.

8/ FY 2002 includes $1,129,000 NCI breast cancer stamp funds.

9/ FY 2004 OD total includes $35 million in Roadmap funds for later distribution to ICs.

**NATIONAL INSTITUTES OF HEALTH**

Budget Mechanism - Total

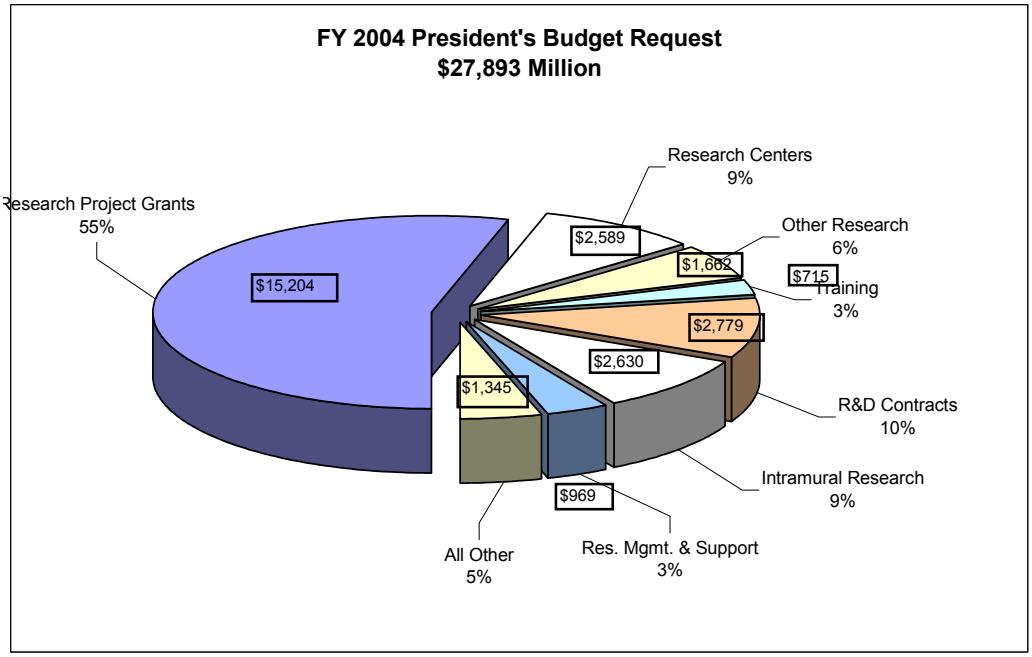
| MECHANISM | FY 2002 Actual 1/ | | FY 2003 Amended President's Budget | | FY 2004 Estimate | |
|---|---|---|---|---|---|---|
| Research Grants: | No. | Amount | No. | Amount | No. | Amount |
| Research Projects: | | | | | | |
| Noncompeting | 24,866 | $9,084,902,000 | 26,195 | $9,968,929,000 | 26,958 | $10,621,302,000 |
| Administrative supplements | (2,126) | 221,259,000 | (1,684) | 163,544,000 | (1,698) | 161,141,000 |
| Full funded | 0 | 0 | 0 | 0 | 322 | 179,222,000 |
| Single year | 9,471 | 3,208,053,000 | 10,165 | 3,612,599,000 | 10,187 | 3,639,930,000 |
| Subtotal, competing | 9,471 | 3,208,053,000 | 10,165 | 3,612,599,000 | 10,509 | 3,819,152,000 |
| Subtotal, RPGs | 34,337 | 12,514,214,000 | 36,360 | 13,745,072,000 | 37,467 | 14,601,595,000 |
| SBIR/STTR | 1,894 | 502,809,000 | 1,949 | 552,985,000 | 2,053 | 602,179,000 |
| Subtotal, RPGs | 36,231 | 13,017,023,000 | 38,309 | 14,298,057,000 | 39,520 | 15,203,774,000 |
| Research Centers: | | | | | | |
| Specialized/comprehensive | 919 | 1,600,861,000 | 961 | 1,866,451,000 | 983 | 2,008,083,000 |
| Clinical research | 96 | 257,285,000 | 100 | 273,319,000 | 100 | 284,820,000 |
| Biotechnology | 55 | 112,149,000 | 58 | 123,979,000 | 61 | 129,981,000 |
| Comparative medicine | 48 | 94,445,000 | 71 | 101,503,000 | 74 | 106,058,000 |
| Research Centers in Minority Institutions | 19 | 52,188,000 | 19 | 57,176,000 | 19 | 60,080,000 |
| Subtotal, Centers | 1,137 | 2,116,928,000 | 1,209 | 2,422,428,000 | 1,237 | 2,589,022,000 |
| Other Research: | | | | | | |
| Research careers | 3,668 | 459,998,000 | 3,962 | 519,340,000 | 4,040 | 538,396,000 |
| Cancer education | 96 | 26,775,000 | 101 | 29,206,000 | 105 | 30,206,000 |
| Cooperative clinical research | 441 | 360,040,000 | 469 | 395,748,000 | 480 | 401,376,000 |
| Biomedical research support | 184 | 128,847,000 | 188 | 128,805,000 | 188 | 134,255,000 |
| Minority biomedical research support | 164 | 110,881,000 | 177 | 121,836,000 | 179 | 124,144,000 |
| Other | 1,362 | 359,535,000 | 1,316 | 413,982,000 | 1,356 | 433,868,000 |
| Subtotal, Other Research | 5,915 | 1,446,076,000 | 6,213 | 1,608,917,000 | 6,348 | 1,662,245,000 |
| Total Research Grants | 43,283 | 16,580,027,000 | 45,731 | 18,329,402,000 | 47,105 | 19,455,041,000 |
| Research Training: | FTTPs | | FTTPs | | FTTPs | |
| Individual awards | 2,699 | 102,730,000 | 2,819 | 110,973,000 | 2,835 | 114,850,000 |
| Institutional awards | 14,185 | 550,527,000 | 14,298 | 582,235,000 | 14,362 | 600,676,000 |
| Total, Training | 16,884 | 653,257,000 | 17,117 | 693,208,000 | 17,197 | 715,526,000 |
| Research & development contracts | 1,999 | 1,797,005,000 | 2,397 | 2,430,393,000 | 2,438 | 2,778,952,000 |
| (SBIR/STTR) | (65) | (18,852,000) | (90) | (24,133,000) | (89) | (25,639,000) |
| | FTEs | | FTEs | | FTEs | |
| Intramural research | 6,737 | 2,234,015,000 | 6,818 | 2,548,774,000 | 6,709 | 2,629,842,000 |
| Research management and support | 4,028 | 785,931,000 | 4,367 | 920,120,000 | 4,415 | 968,817,000 |
| Cancer prevention & control | 464 | 486,622,000 | 448 | 539,767,000 | 441 | 551,790,000 |
| Construction | | 117,600,000 | | 457,000,000 | | 0 |
| Library of Medicine | 673 | 274,284,000 | 677 | 305,927,000 | 666 | 316,040,000 |
| Office ot the Director 2/ | 600 | 253,463,000 | 604 | 273,952,000 | 594 | 317,983,000 |
| Subtotal | | 23,182,204,000 | | 26,498,543,000 | | 27,733,991,000 |
| Buildings and Facilities 3/ | | 295,879,000 | | 769,100,000 | | 80,000,000 |
| **Program Total, NIH** | | 23,478,083,000 | | 27,267,643,000 | | 27,813,991,000 |
| Superfund Activities | | 80,725,000 | | 75,774,000 | | 78,774,000 |
| *Budget Authority with Superfund* | | *23,558,808,000* | | *27,343,417,000* | | *27,892,765,000* |
| Type 1 Diabetes 4/ | | -97,000,000 | | -100,000,000 | | -150,000,000 |
| **Total Budget Authority, NIH** | | 23,461,808,000 | | 27,243,417,000 | | 27,742,765,000 |
| (Clinical Trials) | | (2,410,553,000) | | (2,683,113,000) | | (2,769,283,000) |

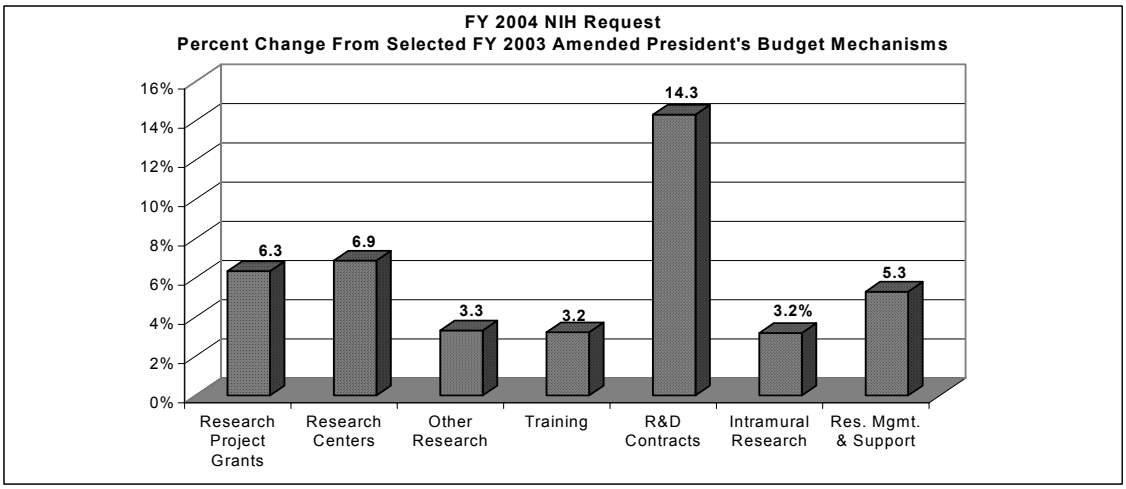
1/ Program FY 2002 total includes $6,880,000 ONDCP transfer; NCI breast cancer stamp funds of $1,129,000.

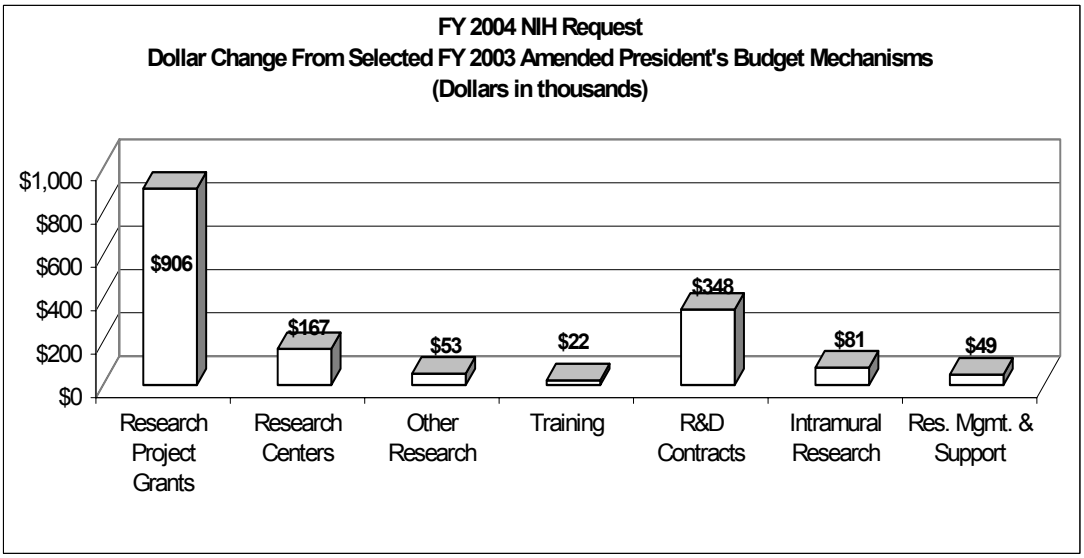
2/ FY 2004 includes $35 million for Roadmap activities to be distributed to the ICs. Excluding this amount, the increase of FY 2004 over FY 2003 is 3.3%.

3/ Buildings and Facilities includes funds only appropriated to this account. Some Institutes and Centers also budget for facilities renovations and associated construction costs in other operating mechanisms, which are not reflected on this line. The PHS Facilities Manual provides specific guidelines for use of operating funds.

4/ Included in NIDDK – FY 02 $97,000,000; FY 03 $100,000,000; FY 04 $150,000,000


FY 2004 President's Budget Request
$27,893 Million
Research Project Grants
55%
$15,204
Research Centers
9%
$2,589
Other Research
6%
$1,662
$715
Training
3%
$2,779
$2,630
R&D Contracts
10%
$1,345
Intramural Research
9%
$969
All Other
5%
Res. Mgmt. & Support
3%


FY 2004 NIH Request
Percent Change From Selected FY 2003 Amended President's Budget Mechanisms
16%
14%
12%
10%
8%
6%
4%
2%
0%
6.3
6.9
3.3
3.2
14.3
3.2%
5.3
Research Project Grants
Research Centers
Other Research
Training
R&D Contracts
Intramural Research
Res. Mgmt. & Support


FY 2004 NIH Request
Dollar Change From Selected FY 2003 Amended President's Budget Mechanisms
(Dollars in thousands)
$1,000
$800
$600
$400
$200
$0
$906
$167
$53
$22
$348
$81
$49
Research Project Grants
Research Centers
Other Research
Training
R&D Contracts
Intramural Research
Res. Mgmt. & Support